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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,908	11/26/2003	Peter Andersen	0459-0752P	5514
2292 7590 02/05/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
SWARTZ, RODNEY P				
ART UNIT		PAPER NUMBER		
1645				
NOTIFICATION DATE		DELIVERY MODE		
02/05/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/723,908

Applicant(s)

ANDERSEN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-18 and 27-50 is/are pending in the application.
- 4a) Of the above claim(s) 28-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-18, 27, 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12, 14-18 and 27-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' Response to Office Action, received 20 November 2008, is acknowledged. Claims 1, 2 and 3 have been amended.
2. Claims 1-12, 14-18, and 27-50 are pending. Claims 28-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.
3. Claims 1-12, 14-18, 27, and 46-50 are under consideration.

Rejections Withdrawn

4. The objection to claims 1, 2, and 3 is withdrawn in light of the claim amendments.
5. The rejection of claims 1-12, 14-18, 27 and 46-50 under 35 U.S.C. 112, second paragraph, as being indefinite for "a longer polypeptide", is withdrawn in light of the amendment of the claims.

Rejections Maintained

6. The rejection of claims 1-12, 14-18, 27 and 46-50 under 35 U.S.C. 112, second paragraph, as being indefinite for "immunologically equivalent" is maintained.

Applicants argue that the teachings in the specification, pages 8-10 and 13 disclose that a peptide is "immunologically equivalent" if both peptides satisfy one of property i) through property viii) and therefore the term is clear.

The examiner has considered applicants' argument, but does not find it persuasive. Page 13, lines 1-3 state: In the present context, two polypeptide fragments are immunologically equivalent if they both satisfy property i), property ii), property iii), property v), property vi), property vii), or property viii). The use of the alternative, i.e., "or", permits one polypeptide fragment to satisfy property i) while the second polypeptide fragment satisfies property viii). There is no requirement that the two fragments satisfy the same property.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of the claims is drawn to a substantially pure polypeptide selected from a group consisting of a short peptide of at least seven amino acids and at most 10 amino acids, "and" oligopeptide of at least 11 amino acids and at most 100 amino acids "and" a longer polypeptide of at least 101 amino acids and at most 150 amino acids. Because of the two instances of "and", it is unclear what actually is the Markush group, i.e., are there only two choices, one choice being the combination of the short peptide and the oligopeptide, or are there three choices, short peptide, oligopeptide, and longer polypeptide.

9. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Line 4 of each claim recites "said polypeptide". It is unclear to which preceding polypeptide is being referred. Is it the "substantially pure polypeptide" or the "longer polypeptide"?

10. Claims 1- are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

One embodiment of claims 1 and 2 is drawn to a polypeptide of 7 amino acids which "comprises" an amino acid sequence encoded by a member of the *esat-6* gene family with the proviso that the polypeptide is not selected from a group of 15 members of the *esat-6* gene family.

According to page 3, lines 29-33, there are 26 genes of the *esat-6* gene family. Thus, the claimed polypeptide can be from Rv1036c (SEQ ID NO:7, 112 amino acids long), Rv2348c (SEQ ID NO:13, 108 amino acids long), Rv2653c (SEQ ID NO:15, 107 amino acids long), Rv2654c (SEQ ID NO:17, 81 amino acids long), Rv3020c (SEQ ID NO:19, 97 amino acids long), Rv3444c (SEQ ID NO:21, 100 amino acids long), Rv3445c (SEQ ID NO:23, 125 amino acids long), Rv3890c (SEQ ID NO:25, 95 amino acids long), Rv3891c (SEQ ID NO:27, 107 amino acids long), Rv3904c (SEQ ID NO:29, 90 amino acids long) or Rv3905c (SEQ ID NO:31, 103 amino acids long).

Because the claimed polypeptide of 7 amino acids "comprises" an amino acid sequence encoded by one of the polypeptides listed immediately above, it is unclear how one has a 7 amino acid sequence which "comprises" an amino acid sequence of 81-125 amino acids.

Claims 4-12, 14-18, 27 and 46-50 depend from these claims, but do not clarify the issue.

Conclusion

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

January 30, 2009